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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,292	03/15/2004	Yi-Chao Lee	5422-2	3057

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,292	LEE ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

It is noted that the claims of the instant application have been determined to include linking claims. **Claim 1 link(s) Groups I - VIII**, as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

I. Claims 2-7, drawn to a **method of assessing whether a patient is afflicted with carcinoma** comprising determining the amount of a marker in a patient sample wherein the determination of the amount of marker comprises hybridizing a **polynucleotide** expressed by the marker with an oligonucleotide or polynucleotide that is complementary, wherein the said determination comprises performing a polymerase chain reaction, wherein the said determination comprises performing quantitative real-time reverse transcription-polymerase chain reaction, wherein the said determination comprises the use of a microarray, classified in class 435, subclass 6.

Additionally, Applicants must elect a single nucleic acid sequence for a marker selected from Table 1: SEQ ID NO:1, 3, 5, or 7 as each sequence presents a structurally and functionally *distinct* invention not a species.

II. Claims 2, 3, 8, 9, drawn to a **method of assessing whether a patient is afflicted with carcinoma** comprising determining the amount of a marker in a patient sample wherein the determination of the amount of marker comprises binding a **polypeptide** expressed by the marker with an antibody, classified in class 435, subclass 7.1.

Additionally, Applicants must elect a single amino acid sequence for a marker selected from Table 1: SEQ ID NO:2, 4, 6, or 8 as each sequence presents a structurally and functionally *distinct* invention not a species.

III. Claims 2-7, 10, 11, drawn to a **method of assessing the efficacy of a therapy for inhibiting carcinoma in a patient** comprising determining the amount of a marker in a patient sample wherein the determination of the amount of marker comprises hybridizing a **polynucleotide** expressed by the marker with an oligonucleotide or polynucleotide that is complementary, wherein the said determination comprises performing a polymerase chain reaction, wherein the said determination comprises performing quantitative real-time reverse transcription-polymerase chain reaction, wherein the said determination comprises the use of a microarray, classified in class 435, subclass 6.

Additionally, Applicants must elect a single nucleic acid sequence for a marker selected from Table 1: SEQ ID NO:1, 3, 5, or 7 as each sequence presents a structurally and functionally *distinct* invention not a species.

IV. Claims 2, 3, 8, 9, 10, 11, drawn to a **method of assessing the efficacy of a therapy for inhibiting carcinoma in a patient** comprising determining the amount of a marker in a patient sample wherein the determination of the amount of marker comprises binding a **polypeptide** expressed by the marker with an antibody, classified in class 435, subclass 7.1.

Additionally, Applicants must elect a single amino acid sequence for a marker selected from Table 1: SEQ ID NO:2, 4, 6, or 8 as each sequence presents a structurally and functionally *distinct* invention not a species.

V. Claims 2-7, 12, 13, drawn to a **method of assessing the progression of carcinoma in a patient** comprising determining the amount of a marker in a patient sample wherein the determination of the amount of marker comprises hybridizing a **polynucleotide** expressed by the marker with an oligonucleotide or polynucleotide that is complementary, wherein the said determination comprises performing a polymerase chain reaction, wherein the said determination comprises performing quantitative real-time reverse transcription-polymerase chain reaction, wherein the said determination comprises the use of a microarray, classified in class 435, subclass 6.

Additionally, Applicants must elect a single nucleic acid sequence for a marker selected from Table 1: SEQ ID NO:1, 3, 5, or 7 as each sequence presents a structurally and functionally *distinct* invention not a species.

VI. Claims 2, 3, 8, 9, 12, 13, drawn to a **method of assessing the progression of carcinoma in a patient** comprising determining the

amount of a marker in a patient sample wherein the determination of the amount of marker comprises binding a **polypeptide** expressed by the marker with an antibody, classified in class 435, subclass 7.1.

Additionally, Applicants must elect a single amino acid sequence for a marker selected from Table 1: SEQ ID NO:2, 4, 6, or 8 as each sequence presents a structurally and functionally *distinct* invention not a species.

VII. Claims 2-7, 14, 15, drawn to a **method of assessing the whether the carcinoma has metastasized** comprising determining the amount of a marker in a patient sample wherein the determination of the amount of marker comprises hybridizing a **polynucleotide** expressed by the marker with an oligonucleotide or polynucleotide that is complementary, wherein the said determination comprises performing a polymerase chain reaction, wherein the said determination comprises performing quantitative real-time reverse transcription-polymerase chain reaction, wherein the said determination comprises the use of a microarray, classified in class 435, subclass 6.

Additionally, Applicants must elect a single nucleic acid sequence for a marker selected from Table 1: SEQ ID NO:1, 3, 5, or 7 as each sequence presents a structurally and functionally *distinct* invention not a species.

VIII. Claims 2, 3, 8, 9, 14, 15, drawn to a **method of assessing the whether the carcinoma has metastasized** comprising determining the amount of a marker in a patient sample wherein the determination of the amount of

marker comprises binding a **polypeptide** expressed by the marker with an antibody, classified in class 435, subclass 7.1.

Additionally, Applicants must elect a single amino acid sequence for a marker selected from Table 1: SEQ ID NO:2, 4, 6, or 8 as each sequence presents a structurally and functionally *distinct* invention not a species.

IX. Claims 16-18, drawn to a method for determining, *in vitro*, the effectiveness of a therapeutic agent for treatment of carcinoma, classified in class 435, subclass 4.

Additionally, Applicants must elect a single amino acid sequence or polynucleotide sequence for a marker selected from Table 1: SEQ ID NO:1, 2, 3, 4, 5, 6, 7, or 8, as each sequence presents a structurally and functionally *distinct* invention not a species. The claims will be examined as drawn to the elected invention.

X. Claims 19 in part, 20, drawn to a method for determining ***in vitro*** the carcinogenic potential of a product, classified in class 435, subclass 4.

Additionally, Applicants must elect a single amino acid sequence or polynucleotide sequence for a marker selected from Table 1: SEQ ID NO:1, 2, 3, 4, 5, 6, 7, or 8, as each sequence presents a structurally and functionally *distinct* invention not a species. The claims will be examined as drawn to the elected invention.

XI. Claims 19 in part, 20, drawn to a method for determining ***in vivo*** the carcinogenic potential of a product, classified in class 424, subclass 9.2.

Additionally, Applicants must elect a single amino acid sequence or polynucleotide sequence for a marker selected from Table 1: SEQ ID NO:1, 2, 3, 4, 5, 6, 7, or 8, as each sequence presents a structurally and functionally *distinct* invention not a species. The claims will be examined as drawn to the elected invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-XI are materially distinct methods which differ at least in objectives, method steps and reagents. For example, each Group is drawn to a different objective of assessing whether a patient is afflicted with carcinoma (Groups I and II), assessing the efficacy of a therapy for inhibiting carcinoma in a patient (Groups III and IV), assessing the progression of carcinoma in a patient (Groups V and VI), assessing the whether the carcinoma has metastasized (Groups VII and VIII), determining, *in vitro*, the effectiveness of a therapeutic agent for treatment of carcinoma (Group IX), and determining the carcinogenic potential of a product (Groups X and XI). The Groups that share objectives require different reagents and methods steps to accomplish the objective, for example, Groups I, III, V, and VII detect a polynucleotide expressed by a marker and Groups II, IV, VI, and VIII require different reagents and method steps to detect a polypeptide expressed by a marker. Groups X and XI share an objective, however, each Group utilizes distinct populations either *in vitro* or *in vivo* which require different reagents and methods steps to accomplish the objective. Each of the Groups employs chemically distinct reagents to accomplish different objectives that comprise different method steps. Searching all of the groups with all of the different objectives, method steps, and reagents would invoke a high burden of search.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

SPECIES ELECTION

Species Election for Group IX

This application contains claims directed to the following patentably distinct, structurally and functionally different **therapeutic agent** species of the claimed invention: **chemical compound, antisense DNA, siRNA, protein, peptide, or antibody** (claim 18).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 16 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER